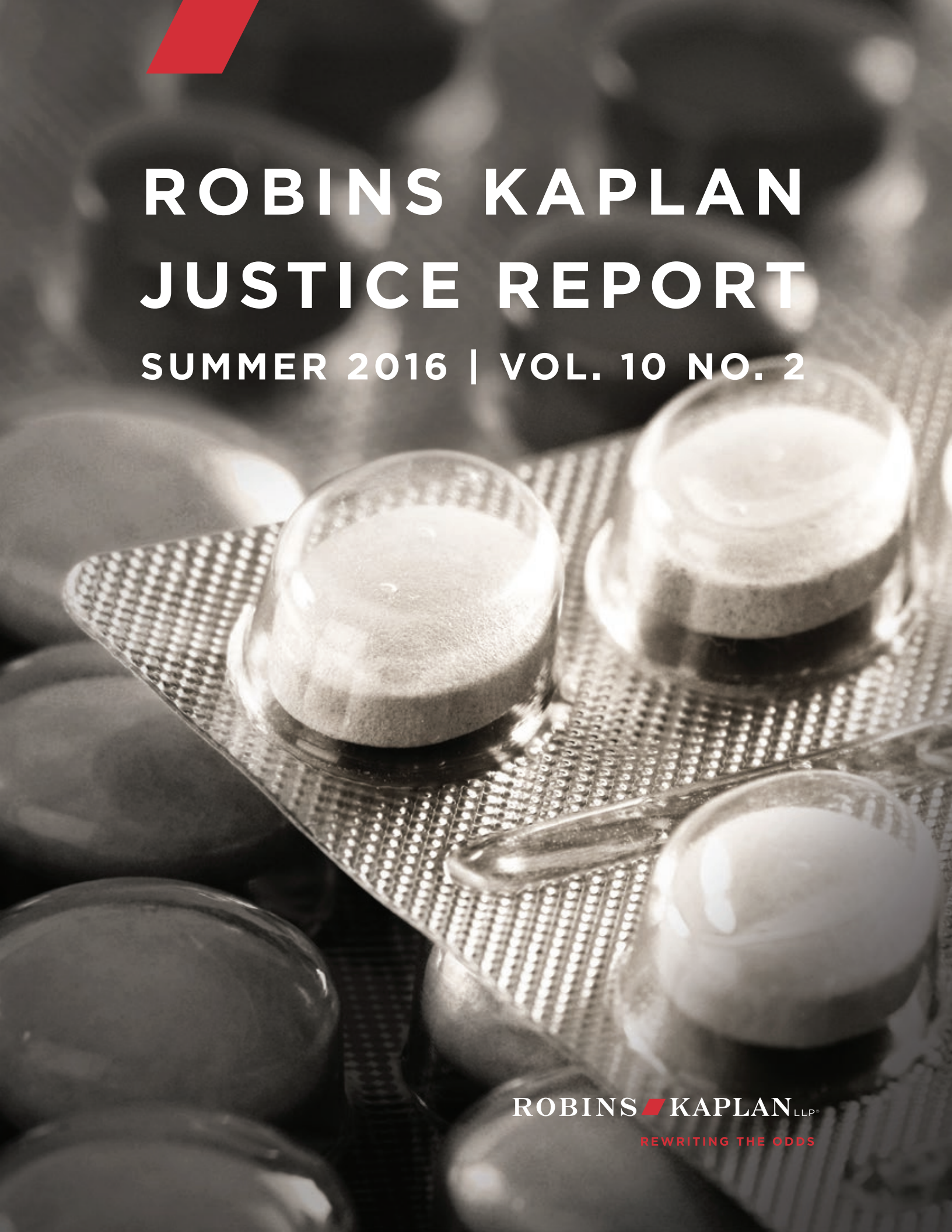

ROBINS KAPLAN JUSTICE REPORT

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ROBINS KAPLAN LLP

REWRITING THE ODDS

INSIDE THIS ISSUE

THE EVOLVING LANDSCAPE OF GENERIC DRUG LIABILITY

BY KATE JAYCOX

KATE JAYCOX

Nearly 80% of prescriptions filled in the United States are filled with generic drugs. If a consumer is injured taking a generic drug, the manufacturer's legal liability is markedly different than if the consumer was taking brand version of the same drug. In the last several years, the Supreme Court has closed most avenues for asserting liability against generic drug manufacturers.

To be approved by FDA, generic drug manufacturers must certify that the generic is chemically and bio-equivalent to a brand-name drug, and that the warning labels are "the same as" those on the brand-name drug.[1] Those injured by prescription drugs often claim a "failure to warn" as required by state law, *i.e.,* the manufacturer failed to warn about the injury suffered.

But, failure-to-warn claims against generic manufacturers are now generally preempted. Here, preemption means that FDA regulations have been found to trump state laws protecting consumers. In *PLIVA, Inc. v. Mensing,* 131 S. Ct. 2657 (2011), the Supreme Court held that it was impossible for generic drug manufacturers to comply with both federal law (allowing only brand manufacturers to change warning labels) and state law (requiring adequate warnings). Thus, the plaintiffs' claims for failure to warn under state law were preempted, and the generic drug manufacturers avoided liability in that case. Similarly, in *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, (2013), the generic manufacturer escaped a $21 million verdict and all liability for a severely injured plaintiff. In *Bartlett*, the Supreme Court held that state-law design defect claims turning on warning adequacy were also preempted in generic cases, rejecting the First Circuit's analysis that the manufacturer could comply with both federal and state laws by choosing not to make the drug at all.

Though manufacturing defect claims are still available against generic manufacturers, the 5 to 4 decisions in *Mensing* and *Bartlett* essentially immunize generic manufacturers from failure-to-warn liability—even if a brand-name manufacturer stopped selling a drug after the drug went generic, even if a risk of injury does not become known until after the drug goes generic, and even if the brand-name manufacturer is held liable for failing to warn consumers of the drug risks.

The strongly worded dissent in *Mensing* decried the "absurd" results of the case, while the majority in *Mensing* sympathized with the "unfortunate hand" plaintiffs face due to federal drug regulation, stating that "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." In *Bartlett*, the Supreme Court stated that congressional action with "'explicit' resolution" on this issue is welcome.

In 2012, both the U.S. Senate and House introduced bills that would have given generic manufacturers the same ability to update or correct warning labels as brand-name manufacturers.[2] The proposed legislation did not emerge from committee, but did garner support from attorneys general from 41 states and U.S. territories urging Congress to amend the law.

With Congress' inability to pass such legislation, FDA began a rulemaking procedure in 2013 to "create parity" between the labels of generic and brand-name drug makers, proposing a rule that would allow generic manufacturers to change their labeling. This would eliminate preemption of generic drug failure-to-warn claims. The proposed rule was to be finalized in late 2014 and then in 2016, but the FDA announced in May 2016 that a new rule will not be finalized until April 2017.

Meanwhile, injured plaintiffs continue to seek help from the courts. While courts are divided, some have recently recognized limited carve-outs to allow consumers to sue generic manufacturers. Example cases include when a generic drug manufacturer fails to update its label after the brand-name counterpart updates the brand label;[3] when a consumer is injured due to a defect with the generic drug packaging;[4] and when a consumer dies from taking a generic drug found to be irremediably dangerous.[5] Furthermore, at least four states have recognized that brand-name manufacturers may be held liable for injuries caused by their generic counterparts.[6]

Generic drug liability is a very fluid area of law, and is likely to evolve further in the upcoming year with new FDA rules and a new Justice on the Supreme Court.

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1. 21 U.S.C. § 355(j)(2)(A)
2. Patient Safety and Generic Labeling Improvement Act, S. 2295 and H.R. 4384, 112th Cong. (2012) (both introduced Apr. 18, 2012).
3. Teva Pharms. USA, Inc. v. Super. Ct., 217 Cal. App. 4th 96 (2013), rev. den. (Sept. 25, 2013) ("Pikerie")
4. Trahan v. Sandoz, Inc., No. 3-13-cv-350-J-34MCR (M.D. Fla. March 26, 2015),
5. *Guvenoz v. Target Corp., Inc.*, 2015 Il. App. 133940 (Ill. App. March 27, 2015)
6. *T.H. v. Novartis Pharms. Corp.*, Super. Ct. No. 37-2013-00070440, (Cal. Ct. App. March 9, 2016); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008); *Teva Pharmaceuticals USA, Inc., v. Superior Court*, 217 Cal. App. 4th 96, 100 (Cal. App. 4th Dist. 2013); *Wyeth v. Weeks*, 159 So. 3d 649, 670 (Ala. 2014), overturned legislatively effective Nov. 1, 2015; *Dolin v. SmithKline Beecham Corp.*, 2014 U.S. Dist. LEXIS 26219, at 12-3 (N.D. Ill. Feb. 28, 2014); *Kellogg v. Wyeth Inc.*, 762 F. Supp. 2d 694, 705 (D. Vt. 2010).

SELECTED RESULTS

$8.5 MILLION IN JUDGMENTS FROM METHADONE-RELATED CAR ACCIDENT

PHIL SIEFF

PATRICK STONEKING

PATRICIA YOEDICKE

Phil Sieff, Patrick Stoneking, and Patricia Yoedicke represented the families of two young men killed in a traffic collision caused by a methadone-impaired driver. The methadone clinic filed a motion to dismiss, which was denied in a "first-of-its kind" ruling in Minnesota that allowed the case to move forward. For the first time in this state, a district court recognized that a clinic owes a duty to the general public when prescribing Schedule II narcotics to patients who get behind the wheel of a car. After two years of litigation and shortly before trial, the clinic agreed to the entry of judgment and to be adjudicated negligent. Insurance coverage continues to be actively litigated.

$1.6 MILLION SETTLEMENT FOR FAILURE TO DIAGNOSE TUMOR

In 2010, our then-16-year-old client was examined by a neurologist after suffering from headaches, nausea, and visual changes. The neurologist stated that she likely suffered from a pseudotumor, but failed to order the MRI scan required to rule out a real tumor. Ultimately, the client's symptoms did not improve over the next two months, and an MRI was eventually ordered. The MRI identified a large tumor in the patient's brain. Unfortunately, during the two-plus-month delay, the tumor applied constant pressure to the client's optic nerve, resulting in permanent vision loss. The defendant in the case argued unsuccessfully that the client's vision loss was caused by her delay in coming back for further evaluation despite no improvement. The client plans to use the settlement proceeds to assist in her future care needs and improve her quality of life.

PETER SCHMIT

BRANDON VAUGHN

SAVE THE DATE: 2016 TRIAL ADVOCACY SEMINAR

The 2016 Trial Advocacy Seminar, hosted by Robins Kaplan's Personal Injury and Medical Malpractice groups, will take place on October 13 at the Radisson Blu in Minneapolis. This year's event is themed "What Trial Lawyers Do Matters," and speakers will focus on the many positive contributions that trial attorneys can make on behalf of the public. CLE credit application is in process.

MEDICAL ERRORS THIRD-LEADING CAUSE OF DEATH IN THE U.S., STUDY FINDS

A recent study published in the BMJ revealed that medical errors are the third-leading cause of death in the United States, accounting for approximately 9.5 percent of all American deaths. This equates to more than 250,000 deaths each year, which is greater than the number of lives lost annually to strokes, respiratory disease, or accidents.

Robins Kaplan has extensive experience with the wide range of negligence and systemic failures that can lead to fatal medical errors. "This study shines a light on the devastating impact that medical errors have on the American public today," said Peter Schmit, Chair of the Personal Injury and Medical Malpractice group, "It's a hazard that patients have faced for far too long, and we work every day to try to bring some measure of justice to those who have been impacted."

Source: "Researchers: Medical errors now third leading cause of death in United States," *The Washington Post*, May 3, 2016

DRUG INVESTIGATION: PERMANENT HAIR LOSS AFTER USING TAXOTERE

BY TROY TATTING

TROY TATTING

Studies and reports have associated permanent hair loss (alopecia) with the use of chemotherapy drug Taxotere (docetaxel).[1] Taxotere is an injectable solution commonly provided to some cancer patients. Although temporary hair loss is a common side effect of chemotherapy, permanent hair loss is not. In certain situations, an alternative and equally effective chemo drug could have been provided that has not been linked to permanent hair loss.[2]

Though marketed in the U.S. since 1996, the Taxotere manufacturer just added language to its U.S. label in December 2015, mentioning reports of permanent hair loss. Ten years earlier, in 2005, the European drug authorities observed that persistent alopecia remained in 3.2% of patients given Taxotere, which is considered a "very common adverse reaction."[3]

1. See, e.g., *Kluger, Permanent Scalp Alopecia Related to Breast Cancer Chemotherapy by Sequential Fluorouracil/Epirubicin/Cyclophosphamide (FEC) and Docetaxel: A Prospective Study of 20 Patients*, Annals of Oncology at 1 (May 9, 2012); Prevezas et al., *Irreversible & Severe Alopecia Following Docetaxel or Paclitaxel Cytotoxic Therapy for Breast Cancer,* 160 Br. J. Dermatology 883-885 (2009); Tallon et al., *Permanent Chemotherapy-Induced Alopecia; Case Report and Review of the Literature*, 63 J. Am. Academy of Derm. 333-336 (2010).

2. Sparano et al., *Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer,* 358(16) New England J. Med. 1663 (Apr. 17, 2008).

3. EMA Scientific Discussion, Taxotere: EPAR at 10, 16 (2005); Taxotere Summary of Product Characteristics (Europe) at 20 (updated Aug. 14, 2015).

OTHER DRUG AND DEVICE INVESTIGATIONS

Robins Kaplan LLP is currently investigating many new potential cases. Please contact our Mass Tort team if you have any questions or know of any individuals whose case should be evaluated.

- **Abilify** – Health Canada recently issued a Safety Alert advising that this atypical antipsychotic—used to treat a variety of disorders, including schizophrenia, bipolar, and depression—may cause impulse-control behaviors, including compulsive gambling. While the drug sold in Canada is now labeled with this warning, no such warning exists on the drug sold in the United States.[1]
- **Benicar** – Popular blood pressure medication can cause intestinal problems known as sprue-like enteropathy, with chronic diarrhea, weight loss, nausea, and vomiting.[2]
- **GranuFlo and Naturalyte Dialysis Products** – Recalled products used in kidney dialysis that can cause metabolic alkalosis, which can lead to cardiopulmonary arrest and death.[3]
- **Hip Implants** – Metallosis and premature device failure with damage to bone or tissue can occur with certain hip implants.[4] Litigating cases involving DePuy ASR, DePuy Pinnacle, Stryker Rejuvenate, Wright Profemur, Wright Conserve, and Biomet M2a-Magnum.
- **Invokana, Farxiga, and Jardiance** – These Type 2 Diabetes drugs can cause ketoacidosis—very elevated blood acid levels—which may require hospitalization.[5]
- **Power Morcellator** – Surgical tool used in hysterectomies and fibroid removal procedures that may promote the spread of undetected uterine cancer.[6]
- **Viagra** – Use is associated with increased risk of melanoma.[7]
- **Xarelto** – Anticoagulant (blood thinner) linked to serious bleeding complications, intracranial hemorrhaging, gastrointestinal bleeding, wound infections from inhibited clotting, and lack of effectiveness in preventing dangerous clotting.[8]
- **Zofran** – This anti-nausea drug is not FDA-approved for use during pregnancy but is often prescribed "off label" for morning sickness and is associated with increased risk of cleft palate and congenital heart defects.[9]

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1. http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/55668a-eng.php
2. http://www.fda.gov/Drugs/DrugSafety/ucm359477.htm; http://www.ncbi.nlm.nih.gov/pubmed/22728033
3. *Dialysate Concentrates Used in Hemodialysis: Safety Communication – Alkali Dosing Errors*, available at www.fda.gov
4. *Concerns about Metal-on-Metal Implants*, available at www.fda.gov
5. *http://www.fda.gov/drugs/drugsafety/ucm446845.htm*
6. FDA discourages use of laparoscopic power morcellation for removal of uterine fibroids, available at www.fda.gov
7. Wen-Qing Li, et al. *Sildenafil Use and Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*. JAMA Intern. Med. (June 2014)
8. Lassan, M.R., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Athroplasty. N. Engl. J. Med. 2008; 358:2776-86; Kakkar, A.K., et al. Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty. Lancet 2008: 372:31-39; Ericksson, B.I., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty. N. Engl. J. Med. 2008; 358;2765-75; Jameson SS, et al. Wound complications following rivaroxaban administration. J. Bone Joint Surg. Am. 2012; 1554-8
9. M. Anderka et al. *Medications Used to Treat Nausea and Vomiting of Pregnancy and Risk of Selected Birth Defects*. Birth Defects Res A Clin Mol Teratol. (Jan. 2012); JT Anderson et al. *Ondansetron use in Early Pregnancy and the Risk of Congenital Malformations – A Register Based Nationwide Cohort Study*. Pharmacoepidemiology and Drug Safety. (Oct. 2013)

FINANCIAL PLANNING AFTER A FAVORABLE VERDICT OR SETTLEMENT

STEVE BRAND

MATTHEW FRERICHS

STEVEN ORLOFF

DENISE RAHNE

No matter a particular client's situation or background, as a lawsuit is approaching an end, involving an estate planning attorney to assist with proper settlement planning can be an invaluable service to the client. Robins Kaplan LLP's Estate and Trust attorneys Steve Brand, Steven Orloff, and Matthew Frerichs are experienced advisors to attorneys and their clients when funds from verdicts or settlements are expected. Our Estate and Trust Litigators, including Denise Rahne, are available to help when disputes arise.

Settlement planning for clients who have been injured, or who have a family member who has been injured, often entails the use of a trust vehicle to hold the monetary award. Different kinds of trusts might be appropriate for a client depending upon his or her individual circumstances. Here are brief summaries of three types of trusts that are commonly used in connection with settlements or verdicts.

SPECIAL NEEDS TRUST

A special needs trust (SNT) is a type of irrevocable trust that is frequently utilized when the injured party is receiving Medicaid or other public benefits. When properly drafted and administered, a SNT can hold assets for the benefit of the injured party and still not count against his or her asset limits for the purposes of Medicaid or Supplemental Security Income (SSI) eligibility. Under current law, a SNT can be created only by the beneficiary's parent, grandparent, legally appointed guardian, or the court. In addition, the trust beneficiary must be "disabled" as defined by the Social Security Act[1] and must be under age 65 when the trust is created. The trust can be funded with only the beneficiary's own assets (including, for example, structured settlement payments) and any distributions from the trust must be for the beneficiary's sole benefit. Upon termination of the trust (usually at the beneficiary's death), and prior to any other distributions, the remaining trust assets must first be used to reimburse the state(s) for Medicaid benefits the beneficiary received during his or her lifetime. In addition to those mentioned above, the law places many other restrictions and prohibitions on the language used in the provisions of a SNT and regarding how and for what purposes the trust assets can be distributed.

SUPPLEMENTAL NEEDS TRUST

Like a special needs trust, a supplemental needs trust (SuppNT) is an irrevocable trust commonly utilized when a person is receiving public benefits. As with a SNT, the beneficiary of a SuppNT must be "disabled" as defined by the Social Security Act.[2] When properly drafted and administered, the assets held in a SuppNT will not count against the trust beneficiary's asset limit for the purposes of Medicaid or SSI eligibility. Unlike an SNT, a SuppNT is funded with the assets of a third party (e.g. the beneficiary's parents). Upon termination of a SuppNT, there is no requirement to reimburse the state for Medicaid benefits that the beneficiary received during his or her lifetime.

IRREVOCABLE SUPPORT TRUST

For an injured person who is not receiving public benefits, an irrevocable support trust can be an effective settlement planning tool. Sometimes called a "Settlement Trust" or a "Settlement Preservation Trust," the purpose of such a trust is to preserve and protect the beneficiary's assets and ensure that the trust assets are used appropriately for the beneficiary's needs. These types of trusts can be drafted in way that is much less restrictive than SNTs or SuppNTs and can be tailored to permit a wide range of permissible distributions for the benefit of the trust beneficiary.

There are many other planning and drafting considerations, legal requirements, and restrictions involving each of the trusts described above—far too many to address here. In particular, SNTs and SuppNTs are heavily regulated and attorneys must be familiar with the relevant laws, rules, and regulations governing these trusts. In addition, the relevant income and estate tax laws must be considered and the client will need practical advice, such as how to choose a suitable trustee. If a practitioner is considering utilizing any type of trust to hold a monetary award for a client or family member of a client, he or she should consult with an experienced estate planning attorney to assist in selecting the appropriate trust vehicle, drafting the trust, funding the trust, and advising on proper trust administration.

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1. In Minnesota, a disability determination may also be made by the State Medical Review Team (SMRT).

2. See FN 1, *supra*.

ATTORNEYS NAMED "2015 ATTORNEYS OF THE YEAR" BY *MINNESOTA LAWYER*

Attorneys Kathleen Flynn Peterson and Brandon Thompson were recently named "2015 Attorneys of the Year" by *Minnesota Lawyer*. This award, given to just 18 individuals, recognizes the recipients' leadership abilities, involvement in noteworthy cases, and commitment to public service. Nominations were vetted and chosen by a panel of five former "Attorney of the Year" recipients.

Kathleen Flynn Peterson is a Partner and former nurse who focuses her practice on medical negligence cases. In addition to being named "Attorney of the Year," Kathleen was included in *Minnesota Lawyers*' "Circle of Excellence," a recognition reserved for attorneys who have repeatedly been named Attorney of the Year. This is Kathleen's third award, having received the honor in 2007 and 2010.

Brandon Thompson is also a Partner who focuses his practice on medical malpractice. Among his most recent achievements was his representation, along with Associate Colin Peterson, of a 51-year-old Minnesota man who became paralyzed during surgery. After a nine-day trial, the jury awarded the man $9.1 million, an amount that will allow him to live more independently and undergo rehabilitation.

The recipients were honored at an awards banquet held on February 18 at the Hyatt Regency hotel in downtown Minneapolis.

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